IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	MDL DOCKET No. 2974 (1:20-md-02974-LMM) **This Document Relates to:** **Alisa Robere, 1:22-cv-01583-LMM,** **Pauline Rickard, 1:21-cv-03861-LMM,** **Melody Braxton, 1:21-cv-00490-LMM**

PLAINTIFFS' OPPOSITION TO TEVA PHARMACEUTICALS USA, INC.'S, TEVA WOMEN'S HEALTH LLC'S, AND TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.'S MOTION FOR CERTIFICATION UNDER 28 U.S.C. § 1292(b)

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INTRODUCTION

Over five years ago, the Judicial Panel on Multidistrict Litigation ("JPML") created this MDL to litigate product liability claims concerning the Paragard. Now, on the eve of the first bellwether trial, Teva seeks to dramatically delay those trials, and stall the entire MDL by moving to certify the Court's preemption ruling for interlocutory appeal pursuant to 28 U.S.C. § 1292(b). Because Teva's motion satisfies none of the requirements for interlocutory appeal, the Court should deny Teva's motion, allowing the long-awaited bellwether trials to proceed as scheduled.

BACKGROUND

The JPML created this MDL on December 16, 2020, and it has subsequently grown to over 3000 individual cases. More cases continue to be filed. The complaints allege, in pertinent part, that the defendants (Teva and Cooper) breached state law by failing to adequately warn that Paragard could break inside of a woman causing severe, sometimes permanent, injury, and requiring surgical removal of device fragments.[1] After more than five years of litigation, the first bellwether trial in this MDL (Pauline Rickard) is finally set to begin on January 20, 2026, just two weeks after Plaintiffs file this response.[2]

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[1] Plaintiffs allege other claims that are not relevant to this opposition—e.g., design defect and fraud.

[2] Teva insisted upon this trial date, despite Plaintiffs seeking a slight extension to accommodate the volume of discovery still outstanding, and trial counsel's

On December 19, 2025, after wading through significant evidentiary and factual material, the Court largely rejected Teva's preemption arguments. After considering Teva's motion (and that of Defendant Cooper), the Court made numerous subsidiary factual determinations before concluding the bellwether Plaintiffs' failure-to-warn claims are not preempted.

Rather than proceeding to trial as has long been contemplated by the parties and the Court, Teva now seeks to significantly delay these cases by requesting a baseless interlocutory review of the Court's preemption ruling. This is simply Teva's latest maneuver to stall this MDL in the same way it has been stalling for years through its numerous and egregious discovery violations.

Plaintiffs now submit this response in opposition and ask the Court to deny Teva's meritless request to certify. If Teva truly believes the Court's preemption decision is flawed, it can raise that issue through a direct appeal after final judgment in the first trial.

LEGAL STANDARD

"Certification for immediate appeal of a non-final order under § 1292(b) is an extraordinary measure, which is permitted only in exceptional circumstances." *BRP Colleague Inc. v. Gillen*, No. 1:20-cv-03695-LMM, 2023 WL 6536242, at *3 (N.D.

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availability. *See* the Parties' letter briefing to the Court on January 21, 2025 and January 23, 2025, respectively. After briefing the issue, Teva's date prevailed.

Ga. Sept. 1, 2023) (quotation omitted); *see also McFarlin v. Conseco Servs., LLC*, 381 F.3d 1251, 1256 (11th Cir. 2004) (interlocutory appeals should be allowed "only in exceptional cases"). Although this Court has discretion on whether to certify a question for interlocutory appeal, *Chattanooga-Hamilton Cnty. Hosp. Auth. v. Walker Cnty.*, No. 4:15-CV-0250-HLM, 2016 WL 9023007, at *2 (N.D. Ga. Apr. 8, 2016), the movant bears the heavy burden to "make the showings necessary to establish a right to interlocutory appeal," *Reid v. Viacom Int'l Inc.*, No. 1:14-CV-1252-MHC, 2017 WL 11634619, at *9 (N.D. Ga. Sept. 22, 2017) (quoting *CSX Transp., Inc. v. Kissimmee Util. Auth.*, 153 F.3d 1283, 1286 (11th Cir. 1998)).

Certification is appropriate only if the movant proves three things: (1) the order "involves a controlling question of law;" (2) there is a "substantial ground for difference of opinion;" and (3) an immediate appeal from the order "may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). Interlocutory appeals are rarely appropriate because the final judgment rule protects the division of labor between district courts and courts of appeals, allowing cases to move through the courts efficiently. *BRP Colleague*, 2023 WL 6536242, at *3 (quoting *McFarlin*, 381 F.3d at 1259). Certifying too many questions for interlocutory appeal threatens those goals. *Id.* "Permitting piecemeal appeals is bad policy, permitting liberal use of § 1292(b) interlocutory appeals is bad policy." *McFarlin*, 381 F.3d at 1259. This is why fact-bound questions are ill-suited for

interlocutory appeals under section 1292(b). *Id.*; *WestRock CP, LLC v. Corrugated Synergies Int'l, LLC*, No. 1:21-cv-05255-LMM, 2025 WL 3083375, at *3 (N.D. Ga. Aug. 14, 2025) (quoting *Simpson v. Carolina Builders Corp.*, 222 F. App'x 924, 925 (11th Cir. 2007)).

ARGUMENT

Teva cannot meet the "high threshold for certification" which is meant "to prevent piecemeal appeals." *Parris v. 3M Co.*, No. 4:21-CV-40-TWT, 2022 WL 2303947, at *3 (N.D. Ga. June 27, 2022). Nor can Teva explain why this Order qualifies as an "exceptional case[]" warranting certification. *Id.* The Court should deny Teva's motion because it satisfies none of the requirements for interlocutory appeal under 28 U.S.C. § 1292(b). It presents no "controlling question of law," no "substantial ground for difference of opinion," and, given the parties are on the eve of trial, no basis to conclude that an immediate appeal would "materially advance the ultimate termination of the litigation." Teva's surprise move to seek interlocutory appellate review should be seen exactly for what it is: an improper last-minute attempt to delay its day of reckoning in this five plus year-old MDL.

I. The Question Teva Wants Certified Is Not A Controlling Issue of Law.

Certification is proper only if the question raised by the motion involves a controlling issue of law. 28 U.S.C. § 1292(b). Here, there is no controlling issue of law because the question involves factual issues that would require the Eleventh

Circuit to comb the record to resolve the issue. Because Teva wholly fails to clear even this first hurdle for certification, the Court should deny its motion.[3]

Interlocutory appeals under section 1292(b) "should be reserved, for situations in which the court of appeals can rule on a pure, controlling question of law without having to delve beyond the surface of the record in order to determine the facts." *Anderson v. S. Home Care Servs., Inc.*, No. 1:13-CV-0840-LMM, 2017 WL 10573993, at *1 (N.D. Ga. Jan. 3, 2017) (quoting *McFarlin*, 381 F.3d at 1259). A question of law is purely legal when it is stated in general terms, *BRP Colleague*, 2023 WL 6536242, at *3 (quoting *McFarlin*, 381 F.3d at 1259), and does not require the court to apply well-established law to the facts or require carefully reviewing the record, *Anderson*, 2017 WL 10573993, at *1. In other words, § 1292(b) is meant to allow appeals when a court of appeals can decide the issue "quickly and cleanly." *Id.* "The antithesis of a proper § 1292(b) appeal is one that turns on . . . whether the district court properly applied settled law to the facts or evidence of a particular case." *Reid*, 2017 WL 11634619, at *10 (quoting *McFarlin*, 381 F.3d at 1259); *see McFarlin*, 381 F.3d at 1259 (to certify a question it must be "stated at a high enough level of abstraction to lift the question out of the details of the evidence or facts of a particular case"). This Court has already held that it will not certify questions that

[3] Additionally, as set forth *infra* at 15–16, resolution of Teva's limited issues would resolve neither this MDL nor the individual cases in which this motion is brought.

require deep engagement with the factual record, which is exactly what Teva is seeking here. *See Anderson*, 2017 WL 10573993, at *1 (citation omitted); *see also Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 317 (2019) (explaining that courts must make factual determinations when deciding preemption questions like those Teva seeks certified).[4] Accordingly, no certification should be granted here.

Teva seeks (at 5) certification on what qualifies as "newly acquired information" under the CBE. This question cannot be decided quickly and cleanly without referring to the factual record; rather, it involves a fact-intensive analysis "that is especially ill suited for interlocutory review." *In re Equifax Inc. Sec. Litig.*, No. 1:17-CV-3462-TWT, 2019 WL 3449673, at *1 (N.D. Ga. July 29, 2019); *see also Lyons v. Boehringer Ingelheim Pharm., Inc.*, 491 F. Supp. 3d 1350, 1363 (N.D. Ga. 2020); *Ridings v. Maurice*, 444 F. Supp. 3d 973, 997–99 (W.D. Mo. 2020); *Roberto v. Boehringer Ingelheim Pharm., Inc.*, No. CPLHHDCV166068484S, 2019 WL 5068452, at *21 (Conn. Super. Ct. Sept. 11, 2019).

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[4] "Generally, questions of law are reviewed de novo and questions of fact, for clear error." *Monasky v. Taglieri*, 589 U.S. 68, 83 (2020). One reason that § 1292(b) limits certification to pure questions of law is because the court of appeals can apply the de novo standard of review. But "when a district court resolves subsidiary factual matters in the course of deciding that ultimate legal question," the proper standard of review is the "clearly erroneous standard." *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 118 F.4th 322, 344 (3d Cir. 2024) (cleaned up). This means that "the clear-error standard of review applies to any subsidiary factual determinations the District Court made" when determining if the CBE regulation preempts a state-law claim. *Id.* at 345.

For example, the Eleventh Circuit would have to evaluate the following issues of fact to resolve the issues concerning their failure to use the CBE process[5]:

- Whether Teva miscoded breakage events and, therefore, diluted and underappreciated the breakage risk, causing the Paragard label to lack an adequate breakage warning. *See* Dkt. No. 59-14,[6] Dec. 5, 2014 Email, attach. MDL2974TWHLLC283409 at 2; attach. MDL2974TWHLLC283410 at 3; Dkt. No. 59-12, Liu Dep. 411:7–415:17, 442:22–443:7.
- Whether Teva's ignoring FDA's instruction to conduct the retroactive adverse events analysis years earlier affected its understanding of the risks associated with Paragard breakage. Dkt. No. 59-8, 2015 Email.
- Whether Teva should have understood the causal connection between breakage and the need for an adequate warning if it had timely followed the FDA's order. *See* Dkt. No. 59-14, Dec. 5, 2014 Email, attach. MDL2974TWHLLC283409 at 2; attach. MDL2974TWHLLC283410 at 3; Dkt. No. 59-12, Liu Dep. 411:7–415:17, 442:22–443:7.

[5] In addition, there are other factual issues related to design defect that the Eleventh Circuit would have to resolve if, as Teva notes in a footnote, the design defect issues are also raised.

[6] All docket entry citations are to Case No. 1:21-cv-03861-LMM (the Rickard case).

In addition, certification would require the Eleventh Circuit to wade into factual issues that Teva waived in its motion for summary judgment but rely on heavily in their request to certify. *Cf. Tobinick v. Novella*, 848 F.3d 935, 944 (11th Cir. 2017) (waived issues are only considered if failing to do so "would result in a miscarriage of justice"). Specifically, in its certification motion, Teva devotes over a page (at 11–12) to discussing Dr. Siyu Liu's 2015 analysis of adverse events related to breakage. Although this argument is critical to the question that Teva wants certified, the word "Liu" appears nowhere in Teva's motion for summary judgment despite the information being available to Teva when it filed its motion. *See* Dkt. No. 42-19, Kessler Rep. at Section VII. The first time Teva mentioned, let alone discussed, Dr. Liu was in its reply to Plaintiffs' opposition to its summary-judgment motion, and it is black letter law that an issue raised for the first time in a reply brief is waived. *United States v. Dicter*, 198 F.3d 1284, 1289 (11th Cir. 1999).[7]

It is difficult to imagine a more fact-bound preemption inquiry than the one at issue here. This Court made innumerable subsidiary factual decisions when denying Teva's preemption summary-judgment motion. On appeal, the Eleventh Circuit

[7] To be clear, Plaintiffs fully intend to press the waiver argument at the Eleventh Circuit if Teva's appeal is ultimately accepted. This will require that court to engage in a fact-bound inquiry into whether overlooking the waiver would result in a miscarriage of justice. Thus, the question Teva seeks to certify is not a pure question of law and the factual nature of Teva's waiver alone is sufficient reason to deny Teva's certification motion.

would review those decisions for clear error. But § 1292(b) certification is not appropriate when the court of appeals would have to undertake that type of clear-error review. Thus, this Court should deny Teva's motion.

II. There Are No Substantial Grounds For Disagreement On Preemption.

A movant satisfies "the requirement that there be substantial ground for difference of opinion" "when (1) the issue is difficult and of first impression, (2) a difference of opinion to the issue exists within the controlling circuit, or (3) the circuits are split on the issue." *BRP Colleague*, 2023 WL 6536242, at *3 (quotation omitted). None of these requirements are met here.

Although Teva might disagree with the Court's preemption order, that does not automatically mean that there are "substantial grounds" to disagree with the Court's order. "[W]hen deciding whether the issue for appeal is truly one on which there is a substantial ground for dispute," district courts must examine the "strength" of the opposition's arguments. *BRP Colleague*, 2023 WL 6536242, at *3 (quotation omitted). However, "[n]either the mere lack of authority on the issue nor the claim that the district court's ruling is incorrect constitutes a substantial ground for difference of opinion." *Anderson*, 2017 WL 10573993, at *3 (quoting *In re Scientific-Atlanta, Inc. Sec. Litig.*, No. 01-CV-1950-RSW, 2003 WL 25740734, at *1 (N.D. Ga. Apr. 15, 2003)); *Benjamin v. Experian Info. Sols., Inc.*, No. 1:20-CV-2466-

RWS, 2021 WL 8571657, at *1 (N.D. Ga. Dec. 14, 2017); *Chattanooga-Hamilton Cnty. Hosp. Auth.*, 2016 WL 9023007, at * 2; *Reid*, 2017 WL 11634619, at *10.

As the Court recognized at summary judgment, the standards for "clear evidence" preemption and "newly acquired information" are well established by the Supreme Court and the FDA. *See* Dkt. No. 137 at 8–9. There is no split of authority on these points. Teva attempts to manufacture a dispute by improperly recasting the issue as whether "after-acquired" data analysis can qualify as "newly acquired information"; this argument fails however because the adverse event data at issue was in Teva's possession well before each of the Plaintiffs' Paragard implantation. While Teva's tardy analysis of this data may have occurred after the Plaintiffs received their implants, sufficient similar data was received before the implants thereby allowing Teva to identify a risk "*dating back to the previous NDA holder* – of a different type and greater frequency of breakage than previously identified." *Id.* at 10 (emphasis added). Teva simply chose to ignore it. No circuit—including the Eleventh Circuit—has held otherwise. Accordingly, there is no "substantial ground for difference of opinion."

First, Teva's argument on "after acquired" versus "newly acquired" misunderstands what is a question of first impression. A question of first impression is one in which no other court has considered the issue. *Cf. United States v. Rogers*, 312 F.3d 1284, 1285 (11th Cir. 2002) (per curiam) (distinguishing between a

question of first impression and a "question of first impression *in this circuit*" (emphasis added)). Teva acknowledges (at 8) that some courts have held, as this Court did, specifically that "information that could have or should have been acquired earlier—could satisfy the CBE regulation and foreclose a federal preemption defense." (citations omitted). This is not an issue of first impression.

Second, even if this were a question of first impression, that fact alone is insufficient to certify the question. *Ga. State Conf. of the NAACP v. Fayette Cnty. Bd. of Comm'rs*, 952 F. Supp. 2d 1360, 1362 (N.D. Ga. 2013). There must also be a "*substantial* ground for dispute," *id.*, and Teva wholly fails to make this showing. Teva simply wants a "better interpretation" of the CBE regulation; that is, Teva wants an interpretation that fits its narrative. Mot. at 12. This "better interpretation," Teva contends, has been adopted by district courts in other circuits. But differences in interpretations by "district courts *outside* the Eleventh Circuit" of what qualifies as newly acquired information "does not present a material difference of opinion warranting interlocutory review" because "there is no apparent disagreement on this issue *within* the Eleventh Circuit." *Aiuto v. Publix Super Mkts., Inc.*, No. 1:19-CV-04803-LMM, 2020 WL 10054617, at *2 (N.D. Ga. May 14, 2020).

The cases Teva cites to support its preemption argument are all inapposite. None of the cited cases dealt with information or analysis that showed a causal relationship between the subject drug and the plaintiffs' injuries, which is what the

information in this case shows. *E.g.*, *Gayle v. Pfizer, Inc.*, 452 F. Supp. 3d 78, 88 (S.D.N.Y. 2020) (finding that the adverse event reports were not "newly acquired information" because the adverse reports did "not reach any conclusions regarding a causal association"); *In re Gardasil Prods. Liab. Litig.*, 770 F. Supp. 3d 893, 908–11, 919 (W.D.N.C. 2025) (finding that the adverse reports did not amount to "newly acquired information" because the reports were accepted without determining whether the vaccine caused the adverse event). In contrast, adverse events related to Paragard breakage have only one potential cause—the Paragard breaking inside a woman. This means that for every adverse event reported to Teva for Paragard breakage, causation was a given. That makes both Dr. Liu's report and the adverse events reports showing Paragard breakage newly acquired information that satisfies the causal requirement for CBE regulation purposes.[8] *See* 21 C.F.R. § 314.70(c)(6)(iii).

Teva also incorrectly asserts (at 10–11) that the Court relied on Plaintiffs' expert report as newly acquired information. This misrepresents both the basis of Plaintiffs' expert opinions and the Court's order. Dr. Kessler reviewed *then existing* information in Teva's control concerning adverse events associated with Paragard breakage. He opined that those adverse events, all received *prior* to Plaintiffs'

[8] The regulation defines "Newly acquired information" to include "reports of adverse events." 21 C.F.R. § 314.3(b).

Paragard implants, constituted sufficient new data to support a CBE change. Furthermore, Dr. Kessler opined that the intentional or incompetent miscoding practices at Teva related to device breakage led to the "accumulation of miscoded breakage-related adverse reports over time." Dkt. No. 137 at 9. Had Teva not miscoded the breakage complaints, it should have recognized the accumulation of breakage complaints prior to the Paragard implants in each of the Plaintiffs. This is a far cry from Teva's conclusion that Dr. Kessler's report, as opposed to the data upon which it relies, is newly acquired evidence.

In sum, Teva's plea for certification is just an attempt to delay final resolution of the bellwether Plaintiffs' cases and forward progress and ultimate resolution of this MDL. While Teva may fear at least one or more juries will find that it violated state law, that is not a substantial ground for disagreement permitting interlocutory appeal. Thus, Teva has failed to satisfy the second requirement for certification.

III. Interlocutory Appeal Would Not Materially Advance the Litigation.

Even if Teva's motion did not fail for the reasons outlined above, it would fail because certification of this question would not materially advance the litigation. "An interlocutory appeal will materially advance the termination of the litigation if it promises to advance the time for trial or shorten the time required for trial," but "an interlocutory appeal will not materially advance the ultimate termination of litigation when discovery has concluded and a case is ready for trial." *Doe ex rel.*

MW v. Dekalb Cnty. Sch. Dist., No. 1:15-CV-03276-RWS, 2019 WL 13292975, at *3 (N.D. Ga. Jan. 17, 2019) (cleaned up); *Benjamin*, 2021 WL 8571657, at *3 (same). Here, as to the bellwether cases, discovery has concluded and the cases are ready for trial. Thus, interlocutory appeal is inappropriate. *Id*.

First, any decision on Teva's proposed certified questions by the Eleventh Circuit would not be controlling for all other cases in this MDL. Teva moved for summary judgment on preemption only for the three bellwether cases set for trial. *See* Ex. A (E-mail from C. Morris to Court). Thus, even if the Eleventh Circuit were to reverse this Court's preemption decision, it would only be binding on the three bellwether Plaintiffs to which Teva expressly limited its motion.

While any potential Eleventh Circuit decision to overturn this Court's preemption order could have some persuasive value when deciding similar motions for certain other Plaintiffs in this MDL, there are still case-specific differences that could significantly decrease (or eliminate) the persuasive value of any decision by the Eleventh Circuit. For instance, even if Dr. Liu's 2015 analysis of historic postmarketing data did not constitute newly acquired information for cases where the Paragard was implanted *before* 2015, such a decision would be inapplicable to cases with implant dates *after* 2015, including those claims that would proceed exclusively against the Cooper Defendants. Additionally, even for those Plaintiffs whose injury accrued before 2015, each of those Plaintiffs may raise additional

factual arguments as to why their individual cases would not be preempted. The facts and arguments in other individual cases in this MDL were not addressed in the underlying summary judgment motions because those motions were limited (by Teva's choice) to only the facts and law that were advanced by these particular bellwether Plaintiffs. Furthermore, the appeal would not even dispose of all claims in the three bellwether cases, and, regardless of the Eleventh Circuit's rulings, those cases would nevertheless have to proceed to trial on the remaining claims against Teva. In short, the most that would happen if the Eleventh Circuit answered the question in Teva's favor would be a remand for further proceedings on preemption; success on this appeal would not "end this litigation entirely," as Teva represented in its motion. Mot. at 4.

Second, the first bellwether trial is set to begin in a mere two weeks—January 20. Plaintiffs have been aggressively working towards trial even in the face of significant, and prejudicial, discovery challenges that have plagued this litigation. The first bellwether is now ready to go and halting the trial at this late date would needlessly delay resolution of the case, and the MDL. Defendants have made clear that they have no genuine interest in resolving the bellwethers or even this MDL. So there is no doubt that trials will be necessary to resolve the claims of the bellwether Plaintiffs and all women injured by Teva's negligent and intentional conduct. Thus,

Teva's motion seeks to simply delay a long-scheduled and inevitable trial date, not advance resolution of this MDL, as represented in their briefing.

Third, it makes sense that courts do not certify interlocutory appeals on the eve of trial, particularly in litigation of this magnitude. With trial a mere two weeks away, significant resources have already been expended: hotel contracts are in place; party, witness, and counsel travel has been arranged; calendars for all involved, including the Court and its staff, have been blocked. Most importantly, the parties and the Court have been aggressively working—even through the holiday season—to get to trial. Certification at this stage would not materially advance this MDL. Instead, it would materially delay its resolution and result in a waste of tremendous resources already expended.

Assuming Teva were allowed to proceed with its appeal, trial would not happen immediately on remand. Rather, it would take months to coordinate the schedules of the Court, the Court's staff, counsel, the parties, and expert witnesses all over again. In short, this last-minute maneuver does not materially advance the litigation; instead, it materially hampers resolution of this MDL. This Court should consider the breadth of which resources may be saved and whether resolution would "substantially shorten the litigation," which, in this case, it would not. *Reid*, 2017 WL 11634619, at *10 (quoting *McFarlin*, 381 F.3d 1251 at 1259).

Teva is also wrong about the quickest path to resolution. Discovery is substantially complete, and the three bellwether cases are trial ready, especially Ms. Rickard who is set for January 20. Her trial will conclude "sooner than the briefing of the issues for an interlocutory appeal." *Benjamin*, 2021 WL 8571657, at *3. The proper course is to proceed to trial. At the end of the day, "the Eleventh Circuit will have a chance to rectify any mistake [Teva] believe[s] the Court has made" when it appeals a final decision. *Anderson*, 2017 WL 10573993, at *3. As Teva also does not satisfy the third prong required for certification, this Court should deny Teva's motion.

CONCLUSION

For all of the reasons set forth herein, the Court should deny Teva's motion.

Dated: January 5, 2026

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